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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SUMITOMO DAINIPPON
PHARMA CO., LTD. and
SUNOVION PHARMACEUTICALS
INC.,

Plaintiffs,

v.

EMCURE PHARMACEUTICALS
LIMITED, *et al.*,

Defendants.

Civil Action No. 15-280 (SRC) (CLW)
Civil Action No. 15-281 (SRC) (CLW)
Civil Action No. 15-6401 (SRC) (CLW)
(Consolidated)

(Filed Electronically)

**SUNOVION'S OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE
THE DECLARATION AND TESTIMONY OF DR. STEPHEN G. DAVIES**

TABLE OF CONTENTS

	Page
INTRODUCTION	1
BACKGROUND TO THE DISPUTE	3
ARGUMENT	6
A. The Appropriate Legal Standard	6
B. Sunovion Did Not Violate Any Local Patent Rule	7
C. Defendants Ignore The <i>Pennypack</i> Factors Which Compel Denial Of Defendants’ Motion	10
CONCLUSION	14

TABLE OF AUTHORITIES

Page(s)

Cases

<i>ABB Air Preheater, Inc. v. Regenerative Envtl. Equip. Co.</i> , 167 F.R.D. 668 (D.N.J. 1996)	7
<i>Dudley v. South Jersey Metal, Inc.</i> , 555 F.2d 96 (3d Cir. 1977)	7
<i>In re Paoli R.R. Yard PCB Litig.</i> , 35 F.3d 717 (3d Cir. 1994)	6
<i>Meyers v. Pennypack Woods Home Ownership Ass’n</i> , 559 F.2d 894 (3d Cir. 1977)	<i>Passim</i>
<i>Source Search Techs., LLC v. Kayak Software Corp.</i> , Civil Action No. 11-3388, 2014 U.S. Dist. LEXIS 1008 (D.N.J. Jan. 6, 2014).....	9
<i>Warner Chilcott Labs. Ir. Ltd. v. Impax Labs., Inc.</i> , Civil Action No. 08-6304, 2010 WL 339034 (D.N.J. Jan. 22, 2010)	1, 6, 7

Other Authorities

L. Pat. R. 4.2	8
L. Pat. R. 4.2(a)	7-8
L. Pat. R. 4.2(b)	3, 7-8
L. Pat. R. 4.2(c)	3, 7-8
L. Pat. R. 4.2(d)	3, 4
L. Pat. R. 4.3(f)	7

INTRODUCTION

When these claim construction proceedings began, Sunovion had hoped the parties would rely on the intrinsic evidence and that there would not be a need for expert witnesses. Defendants, on the other hand, insisted on using an expert to argue their proposed claim construction, leaving Sunovion no choice but to identify an expert of its own. Within three days of each other, Sunovion and Defendants disclosed the names of experts for claim construction. Shortly thereafter on May 4, 2016, the parties filed the Joint Claim Construction and Prehearing Statement, which Defendants admit identifies Sunovion's expert Dr. Stephen G. Davies and the substance of his testimony.¹

Both Sunovion and Defendants submitted declarations from their experts with the opening claim construction briefs and both experts were deposed. In fact, when Defendants received Dr. Davies's declaration months ago, they proceeded as if they had no objection to Dr. Davies.² This makes sense given that both Dr. Davies and Defendants' expert Dr. Stephen W. Baldwin were disclosed in the

¹ *Warner Chilcott Labs. Ir. Ltd. v. Impax Labs., Inc.*, Civil Action No. 08-6304, 2010 WL 339034, at *3 (D.N.J. Jan. 22, 2010) (explaining that by the time of filing the Joint Claim Construction and Prehearing Statement "all expert testimony should be known, or at least discernible, and there is no obvious basis for holding back or reserving additional expert testimony").

² Although Defendants had objected initially to Sunovion's disclosure of Dr. Davies, Defendants' decision to depose Dr. Davies lulled Sunovion into believing the objection was no longer being asserted.

same timeframe and submitted declarations on the same date. Despite these indisputable facts, Defendants seek to exclude Sunovion's expert and rely on their expert's testimony, which absent the testimony of Dr. Davies, would be un rebutted.

The curious timing of Defendants' motion, *after Defendants took Dr. Davies's deposition and on the eve of filing responsive claim construction briefs*, reveals Defendants' true motivation. Defendants seek to exclude Dr. Davies not because of any alleged rule violation, but because the opinion of their expert, Dr. Baldwin, has been exposed as being premised on a flawed and outcome-driven analysis that relies principally on extrinsic evidence. Third Circuit law, however, does not permit exclusion of Sunovion's expert merely because Defendants' expert did not do as well as Defendants had hoped.

The exclusion of important evidence is an extreme discovery sanction guided by the Third Circuit's *Pennypack* factors.³ Those factors consider (1) any prejudice or surprise, (2) the ability to cure any prejudice, (3) any disruption to the orderly and efficient trial of the action, and (4) any bad faith or willfulness on the

³ *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-5 (3d Cir. 1977), *overruled on other grounds*, *Goodman v. Lukens*, 777 F.2d 113 (3d Cir. 1985), *aff'd*, 482 U.S. 656 (1987).

party alleged to have failed to comply with the Court's order.⁴ As explained below, Sunovion did not violate any Local Patent Rules. Moreover, Defendants do not address, or even mention, the *Pennypack* factors.⁵ As a result, Defendants have failed to carry their burden and their motion should be denied.

BACKGROUND OF THE DISPUTE

The dispute regarding expert witnesses began when Defendants served their L. Pat. R. 4.2(b) statements. Each Defendant stated that they planned to rely on expert testimony, but did not identify the witness. In response, Sunovion served its L. Pat. R. 4.2(c) rebuttal statement, hoping that the parties could proceed without the use of expert witnesses, but noting that if Defendants insisted on using experts, Sunovion would “call one or more experts to testify in rebuttal to any expert testimony Defendants may seek to introduce.” (Yakub Exh. 2, at 5.) Defendants’ L. Pat. R. 4.2(c) rebuttal statements maintained that they would rely on expert testimony, but still did not identify the witness.⁶

⁴ *Id.*

⁵ Defendant InvaGen is familiar with the Third Circuit’s *Pennypack* factors. Last year, it argued to this Court that the *Pennypack* factors controlled whether to exclude an expert’s claim construction declaration. (Yakub Exh. 1, at 8-9.) “Yakub Exh. __” refers to exhibits attached to the accompanying August 25, 2016 Declaration of Imtiaz Yakub.

⁶ Teva, for example, stated that it would rely on “[e]xpert opinions” for the level of skill in the art and the claim term at issue. (Yakub Exh. 3, at 3.)

On April 26, 2016, Sunovion sent Defendants a draft of the Joint Claim Construction and Prehearing Statement in order to facilitate the L. Pat. R. 4.2(d) meet and confer. As reflected in the draft, Sunovion again hoped that Defendants would agree to rely only on the intrinsic evidence without any need for competing expert witnesses. (D.I. 98-3, Exh. 3, at 5.)⁷ On April 29, Defendants sent Sunovion proposed revisions to the draft Joint Claim Construction and Prehearing Statement maintaining their desire to use experts and disclosing for the first time the experts they might call: “Defendants anticipate calling Dr. Stephen Baldwin and/or Craig W. Lindsey, Ph.D. . . .” (Yakub Exh. 4.)

Three days later, on May 2, the parties conducted the L. Pat. R. 4.2(d) meet and confer for the purpose of narrowing the claim construction issues and finalizing a Joint Claim Construction and Prehearing Statement for the Court. During the meet and confer, Sunovion tried to convince the Defendants to rely solely on the intrinsic record. Defendants adamantly maintained that they needed expert testimony to support their claim construction. (Yakub Decl., at ¶ 2.) In addition, during the meet and confer, Defendants refused to tell Sunovion whether they would call one or both of the experts identified in their April 29, 2016 draft

⁷ Sunovion also questioned the need for claim construction given that Defendants already admitted infringement in their Paragraph IV Notice Letters that provoked the filing of this consolidated action. (D.I. 81, at 3; D.I. 90, at 1-2.)

Joint Claim Construction and Prehearing Statement. (*Id.*)

Given Defendants' unwillingness to forego reliance on expert testimony, Sunovion explained during the meet and confer that it would also rely on expert testimony to properly set forth the technology at issue and discuss the intrinsic evidence. (Yakub Decl., at ¶ 3.) That same day, and within three days of Defendants' first identification of their possible expert witnesses, Sunovion sent Defendants an e-mail confirming Dr. Davies as its expert. (Yakub Exh. 5.)

Defendants objected to Dr. Davies and Sunovion promptly reached out to Defendants in an effort to address their objection and invited a meet and confer, which Defendants refused. (Yakub Exh. 6.) Pursuant to the Court's Scheduling Order, the parties filed the Joint Claim Construction and Prehearing Statement on May 4, which identifies Sunovion's expert Dr. Davies and the substance of his testimony. (D.I. 81, at 10-11.)

On June 15—42 days after submission of the Joint Claim Construction and Prehearing Statement—the parties submitted opening claim construction briefs accompanied by declarations from Dr. Davies and Dr. Baldwin.⁸ Dr. Davies and Dr. Baldwin were both deposed in July.

⁸ While Defendants had long been expecting a declaration from Sunovion's expert Dr. Davies, Sunovion learned for the first time the day that opening claim

At no point during the scheduling of Dr. Davies's deposition or during the deposition itself did Defendants state an objection to Sunovion's reliance on the opinions set forth by Dr. Davies in his declaration. During his deposition, Dr. Davies explained that Dr. Baldwin's discussion of the technology and claim analysis were misleading and not helpful in understanding how a person of skill would understand Claim 14 of the patent-in-suit. (D.I. 100, at 15-16.)

After Defendants took Dr. Davies's deposition, they again did not state any objection to Dr. Davies. Instead, they waited an additional 25 days and filed the present motion to exclude on the eve of the deadline for filing responsive claim construction briefs.⁹

ARGUMENT

A. The Appropriate Legal Standard

The exclusion of important evidence is "an extreme sanction employed only in the most drastic circumstances." *Warner Chilcott*, 2010 WL 339034, at *3.

Courts in the Third Circuit exercise particular restraint when considering motions to exclude testimony. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791–92 (3d

construction briefs were filed that Defendants had chosen Dr. Baldwin as their expert.

⁹ Defendants' brief does not rely on a single fact that was not known to Defendants more than three months ago when the Joint Claim Construction and Prehearing Statement was filed.

Cir. 1994), *cert. denied*, 513 U.S. 1190 (1995); *Meyers v. Pennypack*, 559 F.2d at 905; *Dudley v. South Jersey Metal, Inc.*, 555 F.2d 96, 99 (3d Cir. 1977). This is because the Third Circuit has “manifested a distinct aversion to the exclusion of important testimony absent evidence of extreme neglect or bad faith on the part of the proponent of the testimony.” *ABB Air Preheater, Inc. v. Regenerative Envtl. Equip. Co.*, 167 F.R.D. 668, 671 (D.N.J. 1996).

In determining whether to exclude expert testimony, the Third Circuit has established four factors for courts to consider: “(1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the court’s order.” *Meyers v. Pennypack*, 559 F.2d at 904-5. The importance of the testimony proposed to be excluded is also a pertinent consideration. *Id.* at 904.

B. Sunovion Did Not Violate Any Local Patent Rule

Sunovion and Defendants identified their claim constructions experts within three days of each other and in advance of submitting the Joint Claim Construction and Prehearing Statement to the Court. *Warner Chilcott*, 2010 WL 339034, at *3 (explaining that by the time of filing the Joint Claim Construction and Hearing

Statement “all expert testimony should be known, or at least discernable, and there is no obvious basis for holding back or ‘reserving’ additional expert testimony”). Defendants’ motion is based on a flawed interpretation of this Court’s Local Patent Rules, which ignores the progressive nature of the rules and the fact that throughout the preliminary claim construction disclosure process, Sunovion advocated for streamlining the parties’ presentations to the Court by avoiding the use of competing expert witnesses.

Tellingly, Defendants’ motion is full of contradiction. Defendants argue that L. Pat. R. 4.2(b) “requires” a party to “identify their *Markman* expert” and that L. Pat. R. 4.3(f) mandates that any evidence not provided in L. Pat. R. 4.2(a)-(c) shall not be included in the Joint Claim Construction and Prehearing Statement. (D.I. 98-1, at 1, 4.) But Defendants ***never identified*** their *Markman* expert in any L. Pat. R. 4.2 statement. Moreover, they added two experts to the Joint Claim Construction and Prehearing Statement who they had not previously identified. In short, Defendants’ own conduct shows that Defendants recognize that the Local Patent Rules provide for progressive disclosure of expert testimony culminating with submission of the Joint Claim Construction and Prehearing Statement.

In their brief, Defendants cite to the Court’s *Source Search* decision as if its ruling is applicable to the present dispute. It is not applicable. *Source Search* involved an expert declaration that was not disclosed until the responsive *Markman*

briefs were filed. *Source Search Techs., LLC v. Kayak Software Corp.*, Civil Action No. 11-3388, 2014 U.S. Dist. LEXIS 1008, at *10 (D.N.J. Jan. 6, 2014). In other words, the expert declaration at issue in *Source Search* was not disclosed until after all exchanges under the Local Rules had already passed and expert discovery had come to a close. *Id.* at *5. In addition, unlike Sunovion, the plaintiff in *Source Search* represented that it did not anticipate calling any witnesses in the submitted Joint Claim Construction and Prehearing Statement. *Id.*¹⁰

Defendants' motion strains to suggest a parallel between their proposed exclusion of expert testimony and Defendants InvaGen's and Emcure's own failure to show good cause under the Local Patent Rules when they sought leave to amend their L. Pat. R. 3.3, 3.4, and 3.6 contentions. (D.I. 98-1, at 5.) Defendants' "sour grapes" argument is unavailing. Instead, the Third Circuit's *Pennypack* factors, which Defendants have utterly failed to address, plainly control this dispute.¹¹

¹⁰ This Court in *Source Search* agreed that "[t]he Rules 'contemplate the disclosure of expert witnesses and their general testimony at two stages—when the preliminary claims construction and extrinsic evidence disclosures are to occur pursuant to L. Pat. R. 4.2 . . . ; and when the Joint Claim Construction and Prehearing Statement is filed with the Court.'" 2014 U.S. Dist. LEXIS 1008 at *7-8 (quoting *Warner Chilcott*, 2010 WL 339034, at *3).

¹¹ Defendant InvaGen also argued to this Court that exclusion of an expert claim construction declaration submitted with a responsive claim construction brief is an

C. Defendants Ignore The *Pennypack* Factors Which Further Compel Denial Of Defendants' Motion

Defendants ignore the Third Circuit's *Pennypack* factors, which both individually and on balance weigh against the extreme sanction of excluding Dr. Davies. For example, as to the first factor, Defendants cannot (and do not) claim any prejudice or surprise by Dr. Davies's declaration and testimony. Dr. Davies was disclosed within the same timeframe that Defendants disclosed their own potential expert witnesses. In addition, Defendants admit that they were aware of Dr. Davies and the substance of his testimony by the time the Joint Claim Construction and Hearing Statement was filed. (D.I. 98-1, at 4.)

The second *Pennypack* factor supports denial of Defendants' motion because any possible prejudice which Defendants could (but did not) allege is already cured. Defendants took Dr. Davies's deposition without any objection to his declaration or the testimony they elicited. In addition, both Sunovion and Defendants had 62 days after receiving the opposing party's expert declaration to work with their own expert to prepare responsive declarations and arguments. Notably, when Sunovion asked Dr. Baldwin whether he planned to provide a

extreme sanction and that any potential prejudice could be cured because, among other things, a *Markman* hearing had not been scheduled and the expert could be deposed. (Yakub Exh. 1, at 9-10.)

response to Dr. Davies's declaration, he did not express the lack of ability or time to do so. Instead, he stated that he was not aware of any plans to submit a responsive declaration and demonstrated that he was unable to identify a single point that he believed was wrong in Dr. Davies's analysis, except his disagreement with Dr. Davies's ultimate conclusion. (Yakub Exh. 7, at 241:25-242:6; 245:8-246:6.)

The third *Pennypack* factor also supports denial of Defendants' motion. Dr. Davies's testimony has not disrupted the schedule or trial of this action. Both Dr. Davies's and Dr. Baldwin's declarations and testimony followed the same sequence set forth in the Court's Scheduling Order (*i.e.*, expert declarations submitted with the parties' opening claim construction briefs followed by their depositions).¹²

The fourth *Pennypack* factor evaluates whether there has been any bad faith or willfulness in the alleged failure to comply with the Court's order. Like the other factors, this factor weighs in favor of denial of Defendants' motion.

Defendants do not allege that Sunovion has acted with any bad faith or willfulness,

¹² By agreement of the parties and without any objection by Defendants, Dr. Davies was deposed a week after the scheduled close of expert discovery relating to claim construction to accommodate his schedule. If anything, that additional week gave Defendants even more time to prepare for Dr. Davies's deposition than they otherwise would have had.

nor could they make such assertions. As explained above, Sunovion's identification of its expert and the substance of his testimony by the time of the Joint Claim Construction and Prehearing Statement is not a late disclosure of expert testimony. Moreover, the record demonstrates that since the beginning of these claim construction proceedings Sunovion has been working to streamline the parties' presentations to the Court by avoiding the use of competing expert witnesses.

Sunovion's reliance on its own expert in opposition to Defendants' expert cannot constitute bad faith or willfulness. On the contrary, Defendants' insistence on relying on an expert witness to support their claim construction makes Dr. Davies's testimony even more critical. Dr. Davies properly frames the technology at issue in this action, discusses the intrinsic record from the perspective of a person of ordinary skill, and exposes Defendants' expert for his outcome-driven analysis that primarily relies on extrinsic evidence. It would be incongruent to allow Dr. Baldwin's flawed claim construction analysis and approach to go un rebutted. *Meyers v. Pennypack*, 559 F.2d at 904 (finding "the importance of the excluded testimony" to be a factor in deciding whether to exclude it).¹³

¹³ Dr. Baldwin's outcome-driven approach has been criticized before. (D.I. 100, at 14.) For example, in *Eli Lilly & Co. v. Zenith Goldline Pharms., LLC*, the court

Given that Defendants have failed to argue any of the *Pennypack* factors in seeking to exclude Dr. Davies, Defendants have not carried their burden on their motion.¹⁴ Accordingly, Defendants' motion should be denied.

devoted an entire section of its opinion, spanning multiple pages, titled, "The Flaws in Dr. Baldwin's Analysis," to deconstruct Dr. Baldwin's flawed obviousness analysis. Civil Action No. IP 99-38-C H/K, 2001 WL 1397304, at *8-11 (S.D. Ind. Oct. 29, 2001).

¹⁴ See *Anspach v. City of Philadelphia*, 503 F.3d 256, 258 n.1. (3d Cir. 2007) (explaining absent compelling circumstances, "failure to raise an argument in one's opening brief waives it.").

CONCLUSION

For the foregoing reasons, Defendants' motion to exclude Dr. Davies's declaration and testimony should be denied.

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